

PATENT Attorney Docket No. EXT-036

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:

Shuber

SERIAL NO.:

09/514,865

GROUP NO.:

1643

FILING DATE:

2/28/00

EXAMINER:

Not yet assigned

TITLE:

METHODS FOR DISEASE DETECTION

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

In accordance with the provisions of 37 C.F.R. §1.97, Applicants hereby make of record the references listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the references are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed (CHECK ONE):

\boxtimes	(1)	within three (3) months of the Filing Date or before the mailing date of the First Office Action on the merits; or
	(2)	after the period defined in (1) but before the mailing date of a Final Rejection or Notice of Allowance, and
		the requisite Statement is below, OR
		the requisite fee under Rule 1.17(p), namely \$240.00, is included herein, or
	(3)	after the mailing date of a Final Rejection or Notice of Allowance but before the payment of the Issue Fee, AND
		Applicant hereby Petitions the Commissioner to accept and consider the attached Information Disclosure Statement, AND
		the requisite Statement is below, AND
		the requisite petition fee due under Rule 1.17(i)(I), namely \$130.00 is included herein

Information Disclosure Statement

Serial No.: 09/514,865

Page 2 of 2

It is respectfully requested that each of the references shown on the attached Form PTO-1449 be made of record in this application.

STATEMENT

As required under §1.97(e), Applicants, through the undersigned, hereby state either that [check the appropriate space]:

- 1. [E]ach item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application **not more than** three months prior to the filing date of the Information Disclosure Statement; or
- [N]o item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

FEE AUTHORIZATION

Should any fee associated with the submission of this paper not be attached hereto as a check, the Commissioner is authorized to charge the missing fee to our Deposit Account, No. 20-0531. Any overpayments should be credited to said Deposit Account.

Date:

Reg. No. 43,526

Tel. No.: (617) 248-7476 Fax No.: (617) 248-7100

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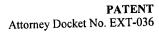
Respectfully subplitted,

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Boston, Massachusetts 02110





IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:

Shuber

SERIAL NO.:

09/514,865

GROUP NO.:

1643

FILING DATE:

February 28, 2000

EXAMINER:

Not yet assigned

TITLE:

Methods for Disease Detection

CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8

I hereby certify that this correspondence, and any documents referred to as enclosed herein, are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to the Assistant Commissioner for Patents, Washington, DC 20231 on this 26th day of June, 2000.

Wendy ///a Wendy Martin

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Submitted herewith are the following:

Transmittal Form (1 page); Information Disclosure Statement (2 pages); Form PTO-1449 (11 pages); Cited references A1-A46, B1-B42 and C1-C94; And return receipt postcard.



TRANSMITTAL FORM

Application Serial Number	09/514,865
Filing Date	February 28, 2000
First Named Inventor	Shuber
Group Art Unit	1643
Examiner Name	Not yet assigned
Attorney Docket No.	EXT-036

				eck all that apply)		Appeal Communication to Board
☐ Fee	Transmittal Form		Copy of Notice to Parts of Applicat (FORM PTO-153	ion	اسا	of Appeals and Interferences
	Check Attached Copy of Fee Transmittal Form		Formal Drawing			Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
	Amendment/Response		Petition Routing and Accompanyi	Slip (PTO/SB/69) ng Petition		Status Letter
	Response to Restriction Requirement and					
	Amendment After Final		To Convert to a	Provisional	⊠	Return Receipt Postcard
	Affidavits/declaration(s)		Application	10415IOHal		Certificate of First Class Mailing
	Letter to Official Draftsperson		Danier of Attach	23/	"	under 37 C.F.R. 1.8
	including Drawings [Total Sheets]		Power of Attorney (Revocation of Prior Powers)			Additional Enclosure(s) (please identify below)
Time U	Petition for Extension of Time Under 37 CFR 1.136(a)		☐ Terminal Disclaimer			
⊠	Information Disclosure Statement		Executed Declaration and Power of Attorney for Utility or Design Patent Application			
	Form PTO-1449 Copies of IDS Citations	Small Entity Statement				
	Certified Copy of Priority Document(s)		Request for Refund			
	Response to Notice to File		After Allowance to Group	e Communication		
	Missing Parts of Application (FORM PTO-1533)					
	Declaration and Power of Attorney For Utility or					
	Design Application (4 pages)					
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	all correspondence to: Patent A	Administra				Respectfully submitted,
	Testa, I	Hurwitz & treet Towe	Thibeault, LLP			Hallrolle
1		reet Towe gh Street	,i	Date: June 23, 200 Reg. No. 43,526	IU	Jennifer A. Camacho
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ATTORNEY DOCKET NO.: EXT-036

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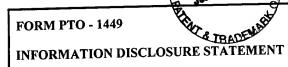
FILING DATE: 2/28/00

GROUP: 1643

U.S. PATENT DOCUMENTS

EXAM.		DOCUMENT			SUB	FILING DATE IF APPROPRIATE	
INIT.		NUMBER	DATE	NAME	CLASS	CLASS	
	A1	4,333,734	6/8/82	Fleisher			10/8/80
	A2	4,535,058	8/13/85	Weinberg et al.			10/1/82
	A3	4,683,195	7/28/87	Mullis et al.			2/7/86
	A4	4,786,718	11/22/88	Weinberg et al.			8/8/85
	A5	4,857,300	8/15/89	Maksem			7/27/87
	A6	4,871,838	10/3/89	Bos et al.			7/23/85
	A7	4,981,783	1/1/91	Augenlicht			4/16/86
	A8	4,982,615	1/8/91	Sultan et al.			4/18/89
	A9	5,087,617	2/11/92	Smith			2/15/89
	A10	5,126,239	6/30/92	Livak et al.			3/14/90
	A11	5,137,806	8/11/92	LeMaistre et al.			12/11/89
	A12	5,196,167	3/23/93	Guadagno et al.			5/9/91
	A13	5,248,671	9/28/93	Smith			12/9/91
	A14	5,272,057	12/21/93	Smulson et al.			12/21/93
	A15	5,302,509	4/12/94	Cheeseman			2/27/91
· · · · · · · · · · · · · · · · · · ·	A16	5,330,892	7/19/94	Vogelstein et al.			3/13/91
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	A18	5,352,775	10/4/94	Albertsen et al.			8/8/91
	A19	5,362,623	11/8/94	Vogelstein et al.			3/31/92
	A20	5,369,004	11/29/94	Polymeropoulos et al.			7/31/92
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	A22	5,380,645	1/10/95	Vogelstein			3/16/89
	A23	5,380,647	1/10/95	Bahar			4/26/93
-	A24	5,382,510	1/17/95	Levine et al.			7/10/92
	A25	5,409,586	4/25/95	Kamahori et al.			8/24/93

EXAMINER DATE CONSIDERED



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U.S. PATENT DOCUMENTS

EXAM. NIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A26	5,458,761	10/17/95	Kamahori et al.			1/27/95
	A27	5,466,576	11/14/95	Schulz et al.			7/2/93
	A28	5,468,610	11/21/95	Polymeropoulos et al.			6/9/93
	A29	5,468,613	11/21/95	Erlich et al.			3/9/90
	A30	5,489,508	2/6/96	West et al.			3/24/93
	A31	5,492,808	2/20/96	de la Chapelle et al.			5/5/93
	A32	5,496,470	3/5/96	Lenhart			5/27/94
	A33	5,508,164	4/16/96	Kausch et al.			10/29/93
	A34	5,512,441	4/30/96	Ronal			11/15/94
	A35	5,514,547	5/7/96	Balazs et al.			2/4/94
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	A38	5,580,729	12/3/96	Vogelstein			6/24/94
	A39	5,589,335	12/31/96	Kearney et al.			8/11/94
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	A40	5,670,325	9/23/97	Lapidus et al.			8/14/96
	A41	5,709,998	1/20/98	Kinzler et al.			12/15/93
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 -	A43	5,741,650	4/21/98	Lapidus et al.			4/21/98
	A44	5,759,777	6/2/98	Kearney et al.			6/2/98
 	A45	5,830,665	11/3/98	Shuber et al.			3/3/97
	A46	5,928,870	7/27/99	Lapidus et al.			6/16/97

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INFORMATION DISCLOSURE STATEMENT

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		T		EIGN PATER		SUB	FILING	ABSTRACT	ENGLISH
EXAM. NIT.		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	CLASS	DATE	ONLY	LANG Y/N
	Bl	0 284 362 A2	9/28/88	EP			3/23/88		
	B2	0 337 498 A2	10/18/89	EP			4/17/89		
	В3	WO 90/09455	8/23/90	PCT			2/13/90		
-	B4	0 390 323 A2	10/3/90	EP			2/20/90		
	B5	0 390 323 A3	10/3/90	EP			2/20/90		
	В6	0 407 789 A1	1/16/91	EP			6/22/90		
	B7	0 407 789 B1	1/16/91	EP			6/22/90		
	B8	WO 92/13103	8/6/92	PCT			1/16/92		
	В9	WO 92/16657	10/1/92	PCT			3/12/92		
	B10	WO 93/18186	9/16/93	PCT			3/1/93		
	B11	WO 93/20233	10/14/93	PCT			3/22/93		
	B12	WO 94/01447	1/20/94	PCT			7/1/93		
	B13	WO 94/09161	4/28/94	PCT			10/20/93		
	B14	WO 94/10575	5/11/94	PCT			10/29/93		_
	B15	WO 94/11383	5/26/94	PCT			11/8/93		
	B16	0 608 004 A2	7/27/94	ЕР		į	8/11/87		
	B17	A-11325/95	10/5/94	AU					
	B18	0 259 031 B1	11/9/94	EP			8/11/87		
	B19	WO 95/07361	3/16/95	PCT			9/9/94		
	B20	WO 95/09928	4/13/95	PCT			9/26/94		
	B21	WO 95/09929	4/13/95	PCT			9/26/94		
	B22	0 648 845 A2	4/19/95	EP			7/2/94		
	B23	WO 95/13397	5/18/95	PCT			11/10/94		
	B24	WO 95/15400	6/8/95	PCT			12/5/94		
	B25	WP 95/16792	6/22/95	PCT			12/13/94	<u> </u>	NO



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FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG Y/N
	B26	WO 95/18818	7/13/95	PCT			1/3/95		
	B27	WO 95/19448	7/20/95	PCT			1/13/95		
	B28	0 664 339 A1	7/26/95	EP			7/7/94		
	B29	WO 95/25813	9/28/95	PCT			3/17/95		
	B30	WO 95/31728	11/23/95	PCT			5/15/95		
	B31	WO 96/01907	1/25/96	PCT			7/10/95		
	B32	WO 96/06951	3/7/96	PCT			8/31/95		
	B33	WO 96/08514	3/21/96	PCT			9/12/95		
	B34	WO 96/12821	5/2/96	PCT			12/19/95		
	B35	WO 96/13611	5/9/96	PCT			10/27/95		
	B36	WO 96/30545	10/3/96	PCT			2/14/96		
	B37	WO 97/09449	3/13/97	PCT			9/2/96		
	B38	WO 97/09600	3/13/97	PCT			9/5/96		
	B39	WO 97/23651	7/3/97	PCT			12/20/96		
	B40	WO97/25442	7/17/97	PCT			1/9/97		
	B41	WO 98/38338	9/3/98	PCT			2/27/98		
	B42	WO 98/58081	12/23/98	PCT	1		6/4/98		

EXAMINER	DATE CONSIDERED



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		FIEMO DATE. 2/20/00
		OTHER ART, JOURNAL ARTICLES, ETC.
EXAM. INIT.		OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
	C1	Aaltonen et al. (1994) "Replication Errors in Benign and Malignant Tumors from Hereditary Nonpolyposis Colorectal Cancer Patients" Cancer Research 54: 1645-1648
	C2	Aaltonen et al. (1998) "Incidence of Hereditary Nonpolyposis Colorectal Cancer and the Feasibility of Molecular Screening for the Disease" The New England Journal of Medicine 338: 1481-1487
	C3	Ausubel et al., (1995), Short Protocols in Molecular Biology, 3d ed., pp. 2-3 -2-12, 3-30 -3-33.
	C4	Bertario et al. (1999) "Risk of Colorectal Cancer Following Colonoscopic Polypectomy" <u>Tumori</u> 85: 157-162
	C5	Beskin et al., (1995), "On the Mechanism of the Modular Primer Effect," Nucleic Acids Research, Vol. 23 No. 15, 2881-2885.
	C6	Blum H.E., (1995) "Colorectal Cancer: Future Population Screening for Early Colorectal Cancer" <u>European Journal of Cancer</u> , Vol. 31A, pp. 1369-1372.
	C7	Bos et al., (May 28, 1987) "Prevalence of ras Gene Mutations in Human Colorectal Cancers," Nature, Vol. 327, pp. 293-297.
	C8	Caldas et al., (July 1, 1994) "Detection of K-ras Mutations in the Stool of Patients with Pancreatic Adenocarcinoma and Pancreatic Ductal Hyperplasia" Cancer Research, Vol. 54, pp. 3568-3573.
	C9	Capozzi et al. (1999) "Evaluation of the Replication Error Phenotype in Relation to Molecular and Clinicopathological Features in Hereditary and Early Onset Colorectal Cancer" <u>European Journal of Cancer</u> 35: 289-295
	C10	Cave et al., (1994) "Reliability of PCR Directly from Stool Samples: Usefulness of an Internal Standard," BioTechniques, Vol. 16, No. 5, pp. 809-810.
	C11	Chapelle (1999) " Testing Tumors for Microsatellite Instability" <u>European Journal of Human Genetics</u> 7: 407-408
	C12	Charlesworth <i>et al.</i> , (September 15, 1994) "The Evolutionary Dynamics of Repetitive DNA in Eukaryotes," Nature, Vol. 371, pp. 215-220.
	C13	Chen et al. (1997) "Microsatellite Instability in Sporadic-Colon-Cancer Patients With and Without Liver Metastases" International Journal of Cancer 74: 470-474
	C14	Coll <i>et al.</i> , (October 1989) "Evaluation of a Rapid Method of Extracting DNA from Stool Samples for Use in Hybridization Assays," <u>Journal of Clinical Microbiology</u> , Vol. 27, No. 10, pp. 2245-2248.
	C15	Coughlin et al. (1999) "Public Health Perspectives on Testing for Colorectal Cancer Susceptibility Genes" American Journal of Preventive Medicine 16: 99-104

EXAMINER	DATE CONSIDERED
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ATTORNEY DOCKET NO.: EXT-036

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		OTHER ART, JOURNAL ARTICLES, ETC. (continued)
EXAM. INIT.		OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
	C16	Cunningham C. and M.G. Dunlop, (1996) "Molecular Genetic Basis of Colorectal Cancer Susceptibility," British Journal of Surgery, Vol. 83, pp. 321-329.
-	C17	Deng et al., (December 20, 1996) "Loss of Heterozygosity in Normal Tissue Adjacent to Breast Carcinomas," Science, Vol. 274, pp. 2057-2059.
	C18	Deuter et al., (1995) "A Method for Preparation of Fecal DNA Suitable for PCR," Nucleic Acids Research, Vol. 23, No. 18, pp. 3800-3801.
	C19	Dib et al., (March 14, 1996) "A Comprehensive Genetic Map of the Human Genome Based on 5,264 Microsatellites," Nature Vol. 380, pp. 152-154.
	C20	Duffy M.J., (1995) "Can Molecular Markers Now be Used for Early Diagnosis of Malignancy?" Clin. Chem,. Vol. 41, No.10, pp. 1410-1413.
	C21	Eguchi et al., (April 15, 1996) "Mutations of the p53 Gene in the Stool of Patients with Resectable Colorectal Cancer," Cancer Supplement, Vol. 77, No. 8, pp. 1707-1710.
	C22	Enari et al., (January 1, 1998) "A Caspase-Activated DNase that Degrades DNA During Apoptosis, and its Inhibitor ICAD," Nature, Vol. 391, pp. 43-50.
	C23	Fearon, E.R., (1995) "16 Molecular Abnormalities in Colon and Rectal Cancer," The Molecular Basis of Cancer, pp. 340-357.
	C24	Grossman et al. (1988), "Colonoscopic Screening of persons With Suspected Risk Factors for Colon Cancer" Gastroenterology 94: 395-400
	C25	Gyllensten U. B., Allen M., (1995) "Sequencing of In Vitro Amplified DNA," Recombinant DNA Methodology II, (Wu, ed.), pp. 565-578.
	C26	Hasegawa et al., (1995) "Detection of K-ras Mutations in DNAs Isolated From Feces of Patients with Colorectal Tumors by Mutant-Allele-Specific Amplification (MASA)," Oncogene, Vol. 10, pp. 1441-1445.
	C27	Hoang et al. (1997) "BAT-26, an Indicator of the Replication Error Phenotype in Colorectal Cancers and Cell Lines" Cancer Research 57: 300-303
	C28	Honchel et al., (1995) "Genomic Instability in Neoplasia," Seminars in Cell Biology, Vol. 6, pp. 45-52.
	C29	Hoss et al., (September 17, 1992) "Excrement Analysis by PCR" Scientific Correspondence pp. 199.
	C30	lino et al. (1999) "DNA Microsatellite Instability in Hyperplastic Polyps, Serrated Adenomas, and Mixed Polyps: a Mild Mutator Pathway for Colorectal Cancer?" Journal of Clinical Pathology 52: 5-9

EXAMINER	DATE CONSIDERED



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		OTHER ART, JOURNAL ARTICLES, ETC. (continued)
EXAM. INIT.		OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
	C31	Iniesta et al. (1998) "Genetic Abnormalities and Microsatellite Instability in Colorectal Cancer" Cancer <u>Detection and Prevention</u> 22: 383-395
	C32	Ishimaru <i>et al.</i> (1995) "Microsatellite Instability in Primary and Metastatic Colorectal Cancers" <u>International</u> <u>Journal of Cancer</u> 64: 153-157
	C33	Jarvinen et al. (1995) "Screening Reduces Colorectal Cancer Rate in Families With Hereditary Nonpolyposis Colorectal Cancer" Gastroenterology 108: 1405-1411
· · · · · · · · · · · · · · · · · · ·	C34	Jernvall et al. (1999) "Microsatellite Instability: Impact on Cancer Progression in Proximal and Distal Colorectal Cancers" <u>European Journal of Cancer</u> 35: 197-201
	C35	Jessup J.M. and G.E. Gallick, (September/October 1992) "The Biology of Colorectal Carcinoma," <u>Current Problems in Cancer pp. 263-328.</u>
	C36	Jonsson et al., (January 1995) "From Mutation Mapping to Phenotype Cloning," Proc. Natl. Acad. Sci., Vol. 92 pp. 83-85.
	C37	Kim et al. (1998) "Microsatellite Instability in Young Patients With Colorectal Cancer" Pathology International 48: 586-594
	C38	Konishi <i>et al.</i> (1996) "Molecular Nature of Colon Tumors in Hereditary Nonpolyposis Colon Cancer, Familial Polyposis, and Sporadic Colon Cancer" <u>Gastroenterology</u> 111: 307-317
	C39	Lamberti <i>et al.</i> (1999) "Microsatellite Instability - a Useful Diagnostic Tool to Select Patients at High Risk for Hereditary Non-Polyposis Colorectal Cancer: A Study in Different Groups of Patients With Colorectal Cancer" <u>Gut</u> 44: 839-843
	C40	Lengauer et al., (December 17, 1998) "Genetic Instabilities in Human Cancers," Nature, Vol. 396, pp. 643-649.
	C41	Leong <i>et al.</i> , (1993) "Detection of MYCN Gene Amplification and Deletions of Chromosome 1p in Neuroblastoma by In Situ Hybridization Using Routine Histologic Sections," <u>Laboratory Investigations</u> , Vol. 69, No. 1, pp. 43-50.
	C42	Lin et al. (1998) "Colorectal and Extracolonic Cancer Variations in MLH1/MSH2 Hereditary Nonpolyposis Colorectal Cancer Kindreds and the General Population" <u>Diseases of the Colon & Rectum</u> 41: 428-433
	C43	Litia et al., (1992) "Simultaneous Detection of Two Cystic Fibrosis Alleles Using Dual-Label Time-Resolved Fluorometry," Molecular and Cellular Probes, Vol. 6, pp. 505-512.
	C44	Lleonart et al. (1998) "Microsatellite Instability and p53 Mutations in Sporadic Right and Left Colon Carcinoma" American Cancer Society 83: 889-895

EXAMINER	DATE CONSIDERED



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		OTHER ART, JOURNAL ARTICLES, ETC. (continued)
EXAM. INIT.		OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)
	C45	Loktionov A. and I. K. O'Neill, (1995) "Early Detection of Cancer-Associated Gene Alterations in DNA Isolated from Rat Feces During Intestinal Tumor Induction with 1,2-Dimethylhydrazine," International Journal of Oncology, Vol. 6, pp. 437-445.
	C46	Loktionov et al., (February, 1998) "Quantitation of DNA from Exfoliated Colonocytes Isolated from Human Stool Surface as a Novel Noninvasive Screening Test for Colorectal Cancer," Clinical Cancer Research, Vol. 4, pp. 337-341.
	C47	Mao L. et al., (February 2, 1996) "Molecular Detection of Primary Bladder Cancer by Microsatellite Analysis," Science, Vol. 271, pp. 659-662.
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	C49	Naber S. P., (December 1, 1994) "Molecular Pathology Detection of Neoplasia," New England Journal of Medicine, Vol. 331, No. 22, pp. 1508-1510.
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APPLICANT(S): Shuber

SERIAL NO.: 09/514,865

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